



Texas Department of State  
Health Services

**REGULATORY LICENSING UNIT  
DEVICE DISTRIBUTOR**

**Initial / Renewal License Application**

(Health and Safety Code, Chapter **431**)

Return both the completed application, and non-refundable check or money order made payable to:

Texas Department of State Health Services, RLU,  
Food & Drug Licensing,

P.O. Box 12008, Austin, Texas 78711

For assistance in completing this application call

(512) 834-6727

**DEVICE DIST  
2503**

BUDGET:

**ZZ105**

FUND:

**091**

LICENSE #

**NOTE: Do not submit a device distributor application if physical address of business is located outside of Texas.**

If you are a device manufacturer or a device distributor who is also required to be licensed as a drug distributor or food wholesaler, contact this office at (512) 834-6727 for the correct application.

Name Business is Conducted Under (DBA): \_\_\_\_\_

Physical Address to be Licensed: \_\_\_\_\_

City, County, State, Zip Code: \_\_\_\_\_

Telephone # at address: \_\_\_\_\_ ( ) \_\_\_\_\_

**Type of Operation: (Check all that apply)**

☐ Distributor ☐ Initial Distributor (Importer) ☐ Own-label Distributor ☐ Broker

**Type of Device: (Check all that apply)**

☐ Class I ☐ Class II ☐ Class III ☐ Prescription ☐ OTC ☐ In-vitro diagnostic  
☐ Sterile-Packaged ☐ Tracked ☐ Implantable ☐ Software-driven

**FEE SCHEDULE FOR DEVICE DISTRIBUTOR**

License fees are based on **ALL** gross annual device sales at each licensed place of business. "Distributor" means a person who furthers the marketing of a finished domestic or imported device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user. The term includes an importer or an own-label distributor. The term does not include a person who repackages a finished device or who otherwise changes the container, wrapper, or labeling of the finished device or the finished device package. "Finished Device" means a device, or any accessory to a device, which is suitable for use, whether or not packaged or labeled for commercial distribution.

**GROSS ANNUAL DEVICE SALES**

**FEE FOR INITIAL/RENEWAL LICENSE  
OR CHANGE OF OWNERSHIP**

<input type="checkbox"/> LV1	\$	0.00 - \$ 199,999.99	=	\$ 495.00 per facility
<input type="checkbox"/> LV2	\$	00,000.00 - \$19,999,999.99	=	\$ 1,113.00 per facility
<input type="checkbox"/> LV3	\$	20,000,000.00 - or more	=	\$ 1,1731.00 per facility

☐ **Late Fee** - A person who files a renewal application after the expiration date must pay an additional \$100.00.

**ANY RETURNED CHECKS RECEIVED AFTER EXPIRATION DATE WILL BE  
ASSESSED THE \$100.00 LATE FEE.**

**☐ Exemption from license fee:**

25 TAC 229.427 A person is exempt from the license fees required by this section if the person is a charitable organization, as described in the Internal Revenue Code of 1986, 501(c)(3), to a nonprofit affiliate of the organization, to the extent otherwise permitted by law.

**VERIFICATION:** I swear or affirm that all information in this application is true and correct. I further certify by signature hereon, that I am authorized to execute this document on behalf of the corporation and am eligible to receive a license. If signing this as owner of a sole proprietorship, I am not delinquent in the payment of any child support owed under Chapter 232, Family Code. If signing as a sole proprietor, I certify I have filed the assumed name certificate in appropriate counties pursuant to Business and Commerce Code, Chapter 36. I further certify that I have read and understand Chapter 431 of the Health & Safety Code, the applicable provisions of 25 Texas Administrative Code, Chapter 229, and agree to abide by them.

**Print Name:**

**Title:** ☐ Owner ☐ President  
☐ Partner ☐ Corporate Designee Agent

**sign  
here▶**

**Date:**

**PRIVACY NOTIFICATION:** With few exceptions, you have the right to request and be informed about information that the State of Texas collects about you. You are entitled to receive and review the information upon request. You also have the right to ask the state agency to correct any information that is determined to be incorrect. You may visit our website listed below for more information on the Privacy Notification (Reference: Government Code, Section 552.021, 552.023 and 559.004).

**ALL SIX PAGES OF THE APPLICATION FORM MUST BE COMPLETED BEFORE A LICENSE WILL BE ISSUED.** Please allow 4-6 weeks for processing.

Visit our website at: [www.dshs.texas.gov](http://www.dshs.texas.gov)

Please address **correspondence only** to:  
Texas Department of State Health Services  
RLU, Food and Drug Licensing Group, MC 2835  
PO Box 149347  
Austin, Texas 78714-9347

**PURPOSE OF THIS APPLICATION:** Mark appropriate box to indicate purpose of application, and/or any changes in status of firm. Initial licenses will expire two years from the date of payment receipt by the Department.

☐ **New** Start date of regulated activity: \_\_\_\_\_

☐ **Change of ownership** (including legal entity):

**If change affects multiple licensed locations, contact us at 512-834-6727.**

Change of ownership (including legal entity) requires submission of a new application and fee as listed on page 1.

Previous owner: \_\_\_\_\_ Effective date: \_\_\_\_\_

Previous dba name: \_\_\_\_\_

Previous license number: \_\_\_\_\_

☐ **Amended: If change affects multiple licensed locations contact us at 512-834-6727 prior to submitting application.** Any minor amendment including change of DBA name or change in the location of a licensed place of business requires submission of an amended application and fee as listed on page 1 of the amended application. The current expiration date remains in effect.

☐ Location change (previous location): \_\_\_\_\_

☐ Name Change (previous name): \_\_\_\_\_

☐ Other: \_\_\_\_\_

**Current license number:** \_\_\_\_\_

**Effective date of change:** \_\_\_\_\_

☐ **Renewal:** Renewals are valid from the anniversary date. Failure to submit the renewal fee before the expiration date will result in a delinquency fee for each location and must be remitted before the license will be issued.

☐ **Notice that this firm is out of business.** Date: \_\_\_\_\_

☐ **Not required to license – reason:** \_\_\_\_\_

Sign & date page 1 and return.

**RESPONSIBLE INDIVIDUAL IN CHARGE AT PHYSICAL ADDRESS**

A license cannot be issued for manufacturing or holding of foods for distribution in any room used as living or sleeping quarters; or for the manufacturing, assembling, testing, processing, packing, holding or labeling of drugs and/or devices from any personal residence.

**Please note: Only** drug, device, and/or certificate of authority applicants are required to fill in residence address, driver's license number, and date of birth.

\_\_\_\_\_  
Name & title

\_\_\_\_\_  
Date of birth

\_\_\_\_\_  
Residence address

\_\_\_\_\_  
Driver's license number

**BUSINESS HOURS OF OPERATION** \_\_\_\_\_ **to** \_\_\_\_\_

**WEBSITE/INTERNET ADDRESS:** \_\_\_\_\_

**MAILING ADDRESS INFORMATION** (The license and/or courtesy renewal notice will be sent to the address below).

Mailing name: \_\_\_\_\_

Mailing address: \_\_\_\_\_

City, State, Zip code: \_\_\_\_\_

Name of application preparer (**contact person**): \_\_\_\_\_

Telephone number of contact person: \_\_\_\_\_

Email address of contact person: \_\_\_\_\_

Fax number for contact person: \_\_\_\_\_

**LICENSE HOLDER INFORMATION:** Please enter the 11 digit State Tax Payer's Identification number on file with the Texas Comptroller of Public Accounts. Enter the 9 digit Federal Employee Identification Number (**EIN**).

\_\_\_\_\_  
**Taxpayer number**

\_\_\_\_\_  
**EIN number**

**Please note: Only** for Drug, Device, and/or Certificate of Authority applications:

Has the applicant, licensee, and/or managing officer(s) been convicted of a felony or misdemeanor? ☐ Yes ☐ No

**If yes**, please attach a statement explaining the conviction and include a copy of the driver's license with the application.

For the information below, complete the **box** that applies to the ownership of the license. **In addition, where stated below, residence address, driver's license number, and date of birth are required.**

☐ **Sole Owner / Proprietorship**

Name of sole owner: \_\_\_\_\_

Residence address \_\_\_\_\_ DNL \_\_\_\_\_ DOB \_\_\_\_\_

☐ **Association** ☐ **State Agency**

Name of Association / State Agency: \_\_\_\_\_

Address: \_\_\_\_\_

**Contact person:** \_\_\_\_\_

Residence address \_\_\_\_\_ DNL \_\_\_\_\_ DOB \_\_\_\_\_

**Contact person:** \_\_\_\_\_

Residence address \_\_\_\_\_ DNL \_\_\_\_\_ DOB \_\_\_\_\_

☐ **Partnership** ☐ **LP** ☐ **LLP** ☐ **LTD**

Name of partnership: \_\_\_\_\_

Address of partnership: \_\_\_\_\_

Effective date of partnership: \_\_\_\_\_

(partnership information continued on next page)

**Partner name:** \_\_\_\_\_

Residence address \_\_\_\_\_ DNL \_\_\_\_\_ DOB \_\_\_\_\_

**Partner name:** \_\_\_\_\_

Residence address \_\_\_\_\_ DNL \_\_\_\_\_ DOB \_\_\_\_\_

**Partner name:** \_\_\_\_\_

Residence address \_\_\_\_\_ DNL \_\_\_\_\_ DOB \_\_\_\_\_

☐ **Corporation**      ☐ **LLC**

Effective date of Incorporation: \_\_\_\_\_

Corporation Name: \_\_\_\_\_

Corporation Address: \_\_\_\_\_

**President:** \_\_\_\_\_

Residence address \_\_\_\_\_ DNL \_\_\_\_\_ DOB \_\_\_\_\_

**Officer:** \_\_\_\_\_

Residence address \_\_\_\_\_ DNL \_\_\_\_\_ DOB \_\_\_\_\_

**Officer:** \_\_\_\_\_

Residence address \_\_\_\_\_ DNL \_\_\_\_\_ DOB \_\_\_\_\_

**Registered Agent:** \_\_\_\_\_

Residence address \_\_\_\_\_ DNL \_\_\_\_\_ DOB \_\_\_\_\_